UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

PAMLAB, L.L.C., and BRECKENRIDGE PHARMACEUTICAL, INC., Plaintiffs, v. VIVA PHARMACEUTICAL, INC., Defendant.	Case No. **COMPLAINT FOR VIOLATIONS OF THE LANHAM ACT AND THE WASHINGTON CPA** **JURY TRIAL DEMANDED**

Plaintiffs Pamlab, L.L.C., and Breckenridge Pharmaceutical, Inc., by and through their attorneys, state as follows for their Complaint against Defendant Viva Pharmaceutical, Inc.:

The Parties

1. Plaintiff Pamlab, L.L.C. ("Pamlab") is a limited liability company existing under the laws of the State of Louisiana, with its principal place of business at 4099 Highway 190, Covington, Louisiana, 70433.

SCHWABE, WILLIAMSON & WYATT, P.C.
Attorneys at Law
U.S. Bank Centre
1420 5th Avenue, Suite 3400
Seattle, WA 98101
Telephone 206.622.1711 Fax 206.292.0460

2. Breckenridge Pharmaceutical, Inc. ("Breckenridge") is a corporation existing under the laws of the State of Florida, with its principal place of business at 1141 South Rogers Circle, Suite 3, Boca Raton, Florida, 33487.

3. Defendant Viva Pharmaceutical, Inc. ("Viva") is a corporation existing under the laws of British Columbia, Canada, with its principal place of business at 13880 Viking Place, Richmond, British Columbia, V6V 1K8, Canada.

4. Viva manufactures numerous pharmaceutical products for sale in the United States, works in partnership with companies in the United States in the development of these products, decides on the ingredients and manufacturing specifications in cooperation with companies in the United States, has adopted certain protocols specifically for such products manufactured for the United States market, determines or confirms the expiration date to be assigned to its products sold in the United States, and ships those products to the United States for sale in the United States. Viva also owns at least three United States patents and is prosecuting a number of applications for additional United States patents. Viva has posted on its corporate website a letter from the United States Food and Drug Administration that Viva describes as an "official letter from US FDA . . . indicating that Viva's manufacturing facility has been classified as acceptable by US FDA with regards to compliance to current good manufacturing practices (CGMPs)."

Jurisdiction And Venue

5. This Court has original jurisdiction over the subject matter of this lawsuit under 28 U.S.C. § 1331 and 15 U.S.C. § 1221(a), because it concerns violations of section 43 of the Lanham Act, 15 U.S.C. § 1125. This Court also has original jurisdiction over the state law

SCHWABE, WILLIAMSON & WYATT, P.C.
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U.S. Bank Centre
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Seattle, WA 98101
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claims in this lawsuit under 28 U.S.C. § 1332(a)(2), because Plaintiffs Pamlab and Breckenridge are citizens of American states and Defendant Viva is a citizen of Canada, and the amount in controversy exceeds $75,000, exclusive of interest and costs. This Court also has jurisdiction over the state law claims in this lawsuit under 28 U.S.C. § 1367, because the Court has original jurisdiction over the federal claims, and the state law claims are so related to the federal claims that they form part of the same case or controversy under Article III of the United States Constitution.

6. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391. Upon information and belief, Viva is subject to personal jurisdiction in this district because it has systematic and continuous contacts in this district, and because it manufactures products that are sold and shipped to nationwide retail drug store chains, including those with locations within this judicial district, as well as through nationwide distributors and databases that target this judicial district, and it has purposefully availed itself of the Washington market.

STATEMENT OF FACTS

Plaintiff Pamlab And Its Medical Foods

7. Plaintiff Pamlab is a fully integrated pharmaceutical company, founded over 50 years ago, that is now the largest pharmaceutical company in Louisiana. Pamlab specializes in the development of prescription medical foods that are marketed and sold nationally.

8. Pamlab markets its medical foods as a "brand" pharmaceutical company. As such, Pamlab markets its products directly to physicians, educating physicians concerning the benefits and appropriate uses of its medical food products. Pamlab has spent millions of dollars calling on

SCHWABE, WILLIAMSON & WYATT, P.C.
Attorneys at Law
U.S. Bank Centre
1420 5th Avenue, Suite 3400
Seattle, WA 98101
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tens of thousands of physicians through Pamlab's sales force, providing millions of product samples, publishing articles and advertisements in medical journals, and funding clinical studies.

9. "Medical foods" are to be used by patients under the supervision of a physician or other licensed health professional. Pamlab's medical foods at issue here have been formulated to provide the biologically active form of "folate," needed to meet the distinct nutritional requirements of patients with certain diseases and medical conditions that have been demonstrated to respond to such formulation, and are available by prescription only.

10. Among these products marketed by Pamlab are the five that are relevant to this lawsuit: (1) Metanx®, (2) Cerefolin-NAC®, (3) Neevo® DHA, (4) Deplin® 7.5, and (5) Deplin® 15.

11. Previously, folate supplementation was usually provided via a synthetic form of folic acid (for example, in daily vitamins and dietary supplements). Such synthetic forms of folic acid must undergo several metabolic steps to be converted into their biologically active forms of folate before they can be used in the human body.

12. However, due to their unique formulation, Metanx®, Cerefolin-NAC®, Neevo® DHA, Deplin® 7.5, and Deplin® 15 (collectively, the "Pamlab Products") contain the active form of folate used by the body: 6(S)-5-Methyltetrahydrofolate, also called L-Methylfolate. The presence of the dietary ingredient L-Methylfolate is used by Pamlab as a unique selling point for these products.

13. The unique benefits of this compound come in part from the fact that L-Methylfolate consists of a single diastereoisomer. Many chemical compounds occur as mixtures of two or more diastereoisomers, which have the same chemical composition, but differ

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U.S. Bank Centre
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in the spatial arrangement of the atoms. The various diastereoisomers that are present in such mixtures may have very different properties from one another. In some cases, one diastereoisomer can have a therapeutic effect, while another diastereoisomer is therapeutically ineffective or even harmful. Thus, there are often great benefits to providing patients and consumers with a product that contains only a single diastereoisomer as opposed to a diastereoisomeric mixture.

14. Diastereoisomers are distinguished from one another through naming conventions that reflect their different properties. One such naming convention uses an "L" in the name of the compound to indicate one diastereoisomer, and a "D" in the name of the compound for a different diastereoisomer. The L-form of this compound used in the Pamlab Products – *i.e.*, L-Methylfolate – is superior to the D-form of this compound (D-Methylfolate) because the L-form is the predominant form of folate found in food and the human body. The L-form is the biologically active form of folate and has proven to have a high degree of bioavailability (the rate at which a drug or other substance is available at the targeted place in the body) in humans. The D-form, on the other hand, is of no benefit to humans.

15. In sum, Pamlab's various brand Products are formulated for health care professionals to provide folate, an essential human vitamin of the B complex, in its biologically active form, in amounts shown to be required to meet the distinct nutritional requirements of patients with specific diseases or conditions that have been demonstrated to benefit from such treatment.

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The Nature Of Generic Competition For The Pamlab Products And The Role Of The Pharmaceutical Industry Databases

16. As is well known, pharmaceutical products are often available as a brand product and also as one or more "generic" versions that are required to contain the same active ingredients, dosage form, and strength as the brand product. The market for any particular pharmaceutical product typically begins with one established brand product, which is joined later by one or more lower-cost, generic alternatives.

17. Because the Pamlab Products are dispensed by prescription, in order for a generic product to compete in this market, it must be "substitutable" for one of the Pamlab Products. For this type of pharmaceutical product, a generic may be substituted for a brand product (where permitted) if it is "pharmaceutically equivalent," which means that it must contain the same active ingredients, in the same strengths, and in the same dosage form, as the brand product.

18. Before such substitution can occur, and thus before generic products can be marketed to pharmacies, it is necessary that the generic products be "linked" to the brand product in the industry databases such as First DataBank and Walters Kluwer (Medi-Span). Retail pharmacies, chains, and other purchasers of such products rely on this "linking" in the databases to establish that two different products are, in fact, pharmaceutically equivalent. Based on this "linking," local pharmacists will decide what generic product can be substituted when filling a prescription, and pharmacy purchasers at the national level will decide what generic products to stock for their retail chain nationwide.

19. Unlike drugs, whose equivalency ratings are determined by the FDA and referenced in the FDA publication, the "Orange Book," equivalency determinations for medical foods are based on the honor system, whereby the databases rely primarily on information from

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the generic pharmaceutical companies themselves concerning the active ingredients. Generic medical foods are "linked" by the databases to branded products if the generic company represents that it has the same active ingredients—notwithstanding the actual contents of the products. The listing databases do *not* perform any independent testing on products to confirm the generic company's description of their ingredients. As such, this system depends on truthful reporting by the generic companies of the identity and amount of the active ingredients in their products. There is no "Orange Book" for medical foods.

Plaintiff Breckenridge And The Authorized Generic Products

20. Plaintiff Breckenridge, in contrast to Pamlab, is a generic pharmaceutical company. For more than 25 years, Breckenridge has been in the business of developing and marketing generic pharmaceutical products, and currently markets many such products, all by having them "linked" in the industry databases to the brand products for which they may be substituted.

21. Following the introduction of unauthorized generic competition to the Pamlab Products in 2010, Pamlab first arranged for authorized generic versions of some of these products to be marketed under the Zerxis Pharmaceuticals label. Pursuant to an agreement between Pamlab and Breckenridge, all generic versions that have been authorized by Pamlab (the "Authorized Generic Products") are now marketed by Breckenridge. Pamlab and Breckenridge share in the profits generated by sales of the Authorized Generic Products.

Viva's Pattern And Practice Of Causing Injury To Plaintiffs Through Violation Of The Lanham Act With Successive Products

22. In 2010, Viva manufactured, for sale in the United States by Seton Pharmaceuticals, L.L.C. ("Seton"), several products which Seton marketed as purported generic

SCHWABE, WILLIAMSON & WYATT, P.C.
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Seattle, WA 98101
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equivalents to compete with products marketed by Pamlab and (for one product) by Breckenridge. However, the Seton products did not have active ingredients that were identical to the Pamlab and Breckenridge products, and therefore were not pharmaceutically equivalent and could not be substituted for them. Viva nevertheless cooperated with Seton in providing products that it knew would be marketed in this manner, but with formulations that did not contain the identical active ingredients. Viva also provided an expiration date for Seton to use in marketing its products, without having performed the industry-standard testing to support such a date.

23. This resulted in two lawsuits against Seton (one by Pamlab alone, one by Pamlab and Breckenridge and a patentee), which were subsequently settled, with the Seton products manufactured by Viva being withdrawn from the market.

24. Approximately one year ago, Macoven Pharmaceuticals, LLC ("Macoven") began marketing a folic acid product which it represented to be pharmaceutically equivalent to, and substitutable for, two of Plaintiffs' folic acid products, namely Pamlab's Foltx® and Breckenridge Folbic®. Plaintiffs filed a lawsuit against Macoven alleging both Lanham Act violations and patent infringement.

25. Plaintiffs learned that this product was also being manufactured by Viva, that Viva had again assigned an expiration date to the product without first performing the industry standard testing to support such a date, and that Viva otherwise had not performed standard release testing. Plaintiffs thereupon filed a lawsuit against Viva in this judicial district on January 17, 2012 (Case No. 2:12-cv-00098-MJP), alleging both Lanham Act violations and patent infringement against Viva as well (with patentee Metabolite Laboratories, Inc., as a co-plaintiff).

SCHWABE, WILLIAMSON & WYATT, P.C.
Attorneys at Law
U.S. Bank Centre
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26. These prior lawsuits against Macoven and Viva concerning their folic acid product have now both been settled and dismissed, and Macoven's folic acid product has been withdrawn from the market.

Viva's Current L-Methylfolate Products

27. Upon information and belief, Viva has manufactured for Macoven, and is continuing to manufacture for Macoven, five products that Macoven markets as VitaCirc-B, Alz-NAC, L-Methylfolate PNV DHA, L-Methylfolate Calcium 7.5, and L-Methylfolate Calcium 15 (the Viva-Macoven Products), and which Macoven markets as pharmaceutically equivalent to, and substitutable for, Metanx®, Cerefolin-NAC®, Neevo® DHA, Deplin® 7.5, and Deplin® 15 (the "Pamlab Products").

28. Breckenridge now markets Authorized Generic Products that are identical in every way to each of the Pamlab Products. Thus, to the extent there is generic substitution in filling a prescription for any one of the Pamlab Products, Breckenridge and Macoven are in direct competition.

29. Macoven has been representing to prospective purchasers of the Viva-Macoven Products, who are also customers of Pamlab and Breckenridge, that these products in fact contain the same active ingredients as, and can be substituted for, the Pamlab Products. In the pharmaceutical industry, such representations are understood to mean that Macoven's manufacturer has supplied Macoven with sufficient supporting testing data.

30. Upon information and belief, Viva, as an established participant in the United States pharmaceutical market, is well aware of this industry standard and understanding; moreover, Viva is aware of the regulations governing the manufacture of such products, and of

SCHWABE, WILLIAMSON & WYATT, P.C.
Attorneys at Law
U.S. Bank Centre
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Seattle, WA 98101
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the current Good Manufacturing Practices ("cGMPs") incorporated into federal regulations, that form the regulatory context that would lead purchasers in the United States pharmaceutical industry to believe that Macoven's representations of the active ingredients in the Viva-Macoven Products were supported by adequate testing. However, upon information and belief, Viva continues to make and/or participate in misrepresentations concerning the active ingredients in the Viva-Macoven Products, based on inadequate, incomplete and improper testing.

31. In addition, Viva supported and authorized the affixing of two-year expiration dates to the Viva-Macoven Product, which was necessary to enable this product to compete with Plaintiffs' products, and which represents to the mutual purchasers of Plaintiffs' products and the Viva-Macoven Products that industry-standard testing had been performed. However, upon information and belief, Viva continues to assign expiration dates to these products in contravention of industry standards.

32. Upon information and belief, Viva has participated in, or made on its own, other additional false and/or misleading descriptions and representations of fact, in commerce, that misrepresent the nature, characteristics, and/or qualities of Viva-Macoven Products.

COUNT I
Violation Of The Lanham Act

33. Plaintiffs incorporate the allegations of the preceding paragraphs as though fully set forth herein.

34. Upon information and belief, Viva participated in and contributed to the implicit and/or explicit representations by Macoven that adequate testing had been conducted on the Viva-Macoven Products to confirm that they contain the same active ingredients in the same amounts as, and/or that they are substitutable for, the respective Pamlab Products, and Viva has

SCHWABE, WILLIAMSON & WYATT, P.C.
Attorneys at Law
U.S. Bank Centre
1420 5th Avenue, Suite 3400
Seattle, WA 98101
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made or participated in other explicit and/or implicit representations, which constitute false and/or misleading descriptions and representations of fact, in commerce, that misrepresent the nature, characteristics, and/or qualities of the Viva-Macoven Products, in violation of section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

35. In addition, upon information and belief, the marketing of the Viva-Macoven Products with two-year expiration dates stamped on their package labels, as authorized and directed by Viva, also constitutes false and/or misleading descriptions and representations of fact, in commerce, that misrepresent the nature, characteristics, and/or qualities of the Viva-Macoven Products, in violation of section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

36. Plaintiffs have been injured thereby, in an amount to be determined at trial.

37. Upon information and belief, Viva will continue its violations of the Lanham Act unless such violations thereof are restrained and enjoined by this Court. Should Viva be permitted to continue its false and misleading descriptions and representations of fact and false advertising, Plaintiffs will suffer irreparable injury for which they have no adequate remedy at law.

COUNT II
Violation Of Washington Consumer Protection Act, RCW 19.86

38. Plaintiffs incorporate the allegations of the preceding paragraphs as though fully set forth herein.

39. The false and/or misleading representations described above constitute deceptive acts and practices in trade or commerce that have caused and will cause Plaintiffs to suffer injury to their business and property, in violation of the Washington Consumer Protection Act ("CPA"),

SCHWABE, WILLIAMSON & WYATT, P.C.
Attorneys at Law
U.S. Bank Centre
1420 5th Avenue, Suite 3400
Seattle, WA 98101
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RCW 19.86. Plaintiffs are entitled to actual damages in an amount to be proven at trial, but in any event more than $75,000, exclusive of interest and costs.

40. Defendant's false and misleading representations affect the public interests because they had and have the capacity to injure other persons.

41. Upon information and belief, Viva will continue its violations of the Washington CPA unless such violations thereof are restrained and enjoined by this Court. Should Viva be permitted to continue its false and misleading descriptions and representations of fact and false advertising, Plaintiffs and the public will suffer irreparable injury for which they have no adequate remedy at law.

42. Plaintiffs are also entitled to recover the costs of this suit, including reasonable attorneys' fees, under the Washington CPA.

43. Plaintiffs ask that this Court increase the award of damages up to an amount not to exceed three times the actual damages suffered by Plaintiff, in the maximum amount permitted by law.

WHEREFORE, Plaintiffs request that the Court:

(a) Preliminarily and permanently enjoin Viva, its officers, directors, employees, partners, agents, licensees, servants, successors and assigns, and any and all persons acting in privity or concert with them, from representing, explicitly or implicitly, that any of the Viva-Macoven Products is a pharmaceutical or generic equivalent to, or substitutable for, any of the Pamlab Products, and from making any other false and misleading statements and representations concerning the Viva-Macoven Products, as determined at trial;

SCHWABE, WILLIAMSON & WYATT, P.C.
Attorneys at Law
U.S. Bank Centre
1420 5th Avenue, Suite 3400
Seattle, WA 98101
Telephone 206.622.1711 Fax 206.292.0460

(b) Enter judgment against Viva for compensatory damages by reason of its violation of the Lanham Act, in relation to the Viva-Macoven Products, in an amount to be determined at trial;

(c) Enter judgment against Viva for actual damages by reason of its violation of the Washington Consumer Protection Act, RCW 19.86, in relation to the Viva-Macoven Products, in an amount to be determined at trial, which damages award should be increased up to an amount not to exceed three times the actual damages suffered by Plaintiffs, pursuant to RCW 19.86.090, in the maximum amount permitted by law;

(d) Enter judgment against Viva for the costs of suit, including reasonable attorneys' fees, pursuant to RCW 19.86.090; and

(e) Enter an Order granting Plaintiffs such other and additional relief against Viva as may be just and proper in the circumstances.

DEMAND FOR TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs demand a trial by jury of all issues properly triable to a jury in this case.

Dated this 28th day of January, 2013.

SCHWABE, WILLIAMSON & WYATT, P.C.

By: s/ Johnathan E. Mansfield
Johnathan E. Mansfield WSBA #27779
Attorney for Plaintiffs
Pamlab, L.L.C., and
Breckenridge Pharmaceutical, Inc.

SCHWABE, WILLIAMSON & WYATT, P.C.
Attorneys at Law
U.S. Bank Centre
1420 5th Avenue, Suite 3400
Seattle, WA 98101
Telephone 206.622.1711 Fax 206.292.0460